

Gregory King  
Sr. TA Manager  
Drug Regulatory Affairs

Novartis Pharmaceuticals Corporation  
One Health Plaza  
East Hanover, NJ 07636-1080

Tel 862 778 0495  
Fax 973 781 3966  
Internet: gregory.king@novartis.com



Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**DRAFT GUIDANCE FOR INDUSTRY COMMENTS**

**Noncontraceptive Estrogen Drug Products for  
the Treatment of Vasomotor Symptoms and  
Vulvar and Vaginal Atrophy Symptoms —  
Recommended Prescribing Information for  
Health Care Providers and Patient Labeling  
(November 2005, Revision 4)**

**Docket No: 1998D-0834 (formerly Docket No.  
98D-0834)**

January 12, 2006

As per the instructions provided in the above referenced draft FDA Guidance for Industry, issued for public comment in November 2005, Novartis is providing the attached comments. The comments are provided in tracked-changes form in the guidance document itself (Attachment 1), and accompanied by a document with detailed explanations of the comments in a cross-referenced list (Attachment 2). Novartis appreciates the opportunity to provide comments to this important Guidance document.

If you have any questions or comments regarding this submission, please contact me at (862) 778-0495.

Sincerely,

A handwritten signature in black ink, appearing to read 'G King'.

*for/*  
Gregory King  
Senior Therapeutic Area Manager  
Drug Regulatory Affairs

Submitted in duplicate  
Enclosures

1998D-0834

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